

IRB Review of the Use of Social Media in Research ^{HS}

Social media outlets are revolutionizing the ability of study sponsors and researchers to conduct clinical trials, but the FDA and the OHRP have provided little guidance on their use.

^{HS} Home Study article

LEARNING OBJECTIVE

After reading this article, participants should be able to recognize when and why social media communications must be submitted to the IRB for review.

DISCLOSURES

Cami Gearhart, JD: CEO of Quorum Review IRB.

Social media outlets such as Facebook, Twitter, and YouTube are revolutionizing the ability of study sponsors and researchers to conduct clinical trials, but the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have provided little guidance on the use of these new avenues of communication. Even if new guidance is issued, however, it is unlikely to change the basic principles guiding institutional review boards (IRBs) in ensuring that appropriate safeguards exist to protect the rights and welfare of research participants.

The principles underlying basic human subject protections require that an ethics board or IRB review the content of study-specific communications before they are posted. These principles also require that the IRB understand how the researcher will collect and protect confidential information. With these stipulations in mind, this article explores the application of these principles to the use of social media communications before, during, and after a clinical trial.

Background

The term “social media” refers to Internet-based modes of communication that allow users to interact with the medium (typically a website) or other users of the medium. The term includes social networking websites (such as Facebook, LinkedIn, and Twitter) and social photo and video-sharing websites (such as Shutterfly and YouTube). Social media also can include blogs, podcasts, and text messages.

Social media provide powerful tools for recruiting study participants. The Mayo Clinic recently entered into an arrangement to recruit study participants through an online community of women with heart disease.¹ The study accrued more participants than needed in less than a week.

Social media also can provide powerful tools for the conduct of a trial. A recent study of amyotrophic lateral sclerosis (ALS) was conducted entirely online, and participation was offered to the users of a social network site used by up to 4,300 ALS patients.² Similarly, in 2011, Pfizer launched a trial in which individuals with overactive bladders used computers and smartphones to complete questionnaires and assessments rather than visit a clinic.³

Oversight of Communications

The rules governing clinical trials require close IRB oversight of communications with study subjects, including those made through social media.

Multiple federal departments and agencies have adopted the “Common Rule” of IRB oversight in an effort to promote uniformity, understanding, and compliance with human subject protections.⁴ Regulations governing the protection of human subjects in FDA-regulated research include very similar requirements.⁵ For all studies subject to these provisions, an IRB must prospectively review the study plan, recruitment materials, consent form, and other communications provided to study participants in order to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects.

The rules governing clinical trials require close IRB oversight of communications with study subjects, including those made through social media.

The need for prospective review limits the ability of a researcher to engage in spontaneous interactions in social media. Despite calls to liberalize the rules, federal agencies appear disinclined to repeal the requirement of prospective reviews. OHRP has specified that “[a]lthough websites use a different medium than traditional print or broadcast advertisements the [IRB review] requirements are the same.”⁶ Furthermore, even though the FDA and OHRP solicited comment on changes to the Common Rule, in part because of “[t]he advent of sophisticated computer software programs, the Internet and mobile technology,” none of the agencies’ proposals included dismantling the requirements of prospective review.⁷

Upon reflection, the prospective review of communications that bear on the rights and welfare of potential research subjects is likely a good thing;

there is no reason to think that potential abuses are less likely to occur in the instantaneous use of social media than they are in traditional modes of communication. In fact, the nature of communication through social media is such that it may be more likely to violate basic principles and requirements for communications to study subjects.

A study of self-identified physicians who were heavy users of Twitter found that up to 10% of their postings had content deemed to be unprofessional, including potential privacy violations, profanity, and promotion of unsubstantiated health claims.⁸ Furthermore, social media communications can be long-lasting. As the FDA points out in a recent draft guidance involving communications relating to off-label medications, social media postings are “likely to be available to a broad audience and for an indefinite period of time.”⁹

The FDA held hearings on the use of social media in clinical research in late 2009, and has promised to issue guidance specific to the topic, but no guidance has been issued to date.¹⁰ In the absence of agency guidance specific to social media, IRBs are left to apply existing standards.

This article first reviews the standards by which IRBs currently are required to review the content of communications, including recruitment activities, study tools, retention materials, and post-study communications. Then, a summary of standards for reviewing the collection and use of individuals’ data is provided. Finally, the discussion concludes with an analysis of whether researchers should obtain a “Health Insurance Portability and Accountability Act (HIPAA) waiver” in order to conduct online recruitment.

IRB Review of Content

Recruiting activities are the beginning of the informed consent process and, as such, are subject to IRB review

to ensure that they are accurate and not misleading.^{6,11} The IRB also must ensure that recruitment materials are not “unduly coercive” or promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

The IRB must review all direct advertising for research subjects—“advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study.”^{6,11} In the world of social media, this includes display or banner ads, which are solicitations that often appear along the top or right-hand side of a web page. Direct advertising also includes “rich media advertisements,” which involve an element of interactivity, such as a rollover, scroll bar, or click for more information.

There is no reason to think that potential abuses are less likely to occur in the instantaneous use of social media than they are in traditional modes of communication.

The IRB also should review paid search advertisements, in-text advertisements, and advertisements appearing on social networks such as Facebook, MySpace, and LinkedIn. If a researcher establishes a social network page to promote a study, then that page should be reviewed. Any blog, blog post, tweet, or text that contains study-specific direct advertising should be submitted for review.

The IRB does not need to review study-specific information posted on a website as long as the website format limits the information provided to basic trial information, such as the

title, the purpose of the study, and study locations.^{6,11} Communications that are educational or provide general information, such as postings or podcasts describing symptoms of an underlying disease, do not need to be submitted to the IRB. The IRB also does not need to review study-specific publicity intended for general audiences, such as news stories or financial page advertisements directed toward prospective investors.

Any blog, blog post, tweet, or text that contains study-specific direct advertising should be submitted for review.

The IRB reviews only communications generated by the research sponsor, the research site, or an outsourced agent for them (such as a marketing agency). The IRB does not need to review testimonials, videos, links, or other information communicated by a third party, such as a research participant's post on an investigator's Facebook page. Nevertheless, a researcher should be careful to monitor postings on Internet locations under the researcher's control; in Australia, a court held a life sciences company responsible for failing to remove potentially misleading content posted as testimonials by third parties on the company's Facebook wall and Twitter page.¹²

Thus, the requirement for prospective review limits a researcher's ability to engage in spontaneous dialogue in the course of recruitment. By working with the IRB, however, a researcher should be able to develop a cascading communication plan that outlines possible messages the researcher might desire to text, tweet, blog, or otherwise post in the course of an interactive discussion. If the researcher works closely with the IRB up front, the IRB may be

able to provide expedited review for revisions to the plan.

In addition to reviewing recruitment materials, the IRB must review the content of many other materials delivered to individuals enrolled in a study.¹³ The IRB has authority to approve, require modifications, or disapprove all research activities covered by the regulations, and reviewing "specific research activities" is a function of the IRB.¹³ If a study involves online study tools, then questionnaires, diaries, or other study tools mentioned in the protocol or designed to collect information from the participants should be submitted to the IRB for prospective review. The IRB also should review the content of retention campaigns and the associated communications. Again, the IRB does not need to review educational materials or general informational materials that are not study-specific.

Some sponsors are looking into the use of social media for the dissemination of post-study results. This could be in the form of text posted on a study-specific Facebook page or animated presentations describing study results on YouTube. The use of social media to communicate results of studies is attractive in that it could be quite effective at reaching a large number of individuals. It is important to note that if the study is open, these communications should be submitted for prospective IRB review.

If the study is closed, IRB review is required only in a handful of situations. The communication should be reviewed if it could be characterized as recruitment for a future study. The communication also should be reviewed if it could be considered to be re-initiating study activities. When developing post-study communications, an investigator must be careful not to release individual or identifiable information to maintain compliance with the HIPAA Privacy Rule.¹⁴ Finally, under the HIPAA Privacy Rule, the researcher must return to the IRB (or

a privacy board) for permission to use an individual's contact information to deliver study results if the individual did not provide written authorization of such contact in the study consent form or HIPAA authorization.

IRB Review of Data Collection

One of the defining aspects of social media is that they are interactive. Twitter can be used to solicit information; comments can be posted on a Facebook wall; and individuals can be asked to submit personal data on a website page.

When a researcher collects information about an individual, federal regulations require the IRB to ensure "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."¹⁵ As explained by OHRP, "[i]f identifiable private information is collected via the clinical trial website, the IRB should review plans for protecting the confidentiality of that information. The IRB should ensure that the website clearly explains how identifiable private information might be used."⁶

The requirement for prospective review limits a researcher's ability to engage in spontaneous dialogue in the course of recruitment.

The IRB is primarily concerned with "informational risks," such as the unauthorized disclosure by a researcher of illegal behavior, substance abuse, or chronic illness.¹⁶ Thus, with any use of social media, the IRB will want to understand exactly what information the investigator is collecting, such as names, e-mail addresses, or other identifiable information. The investigator should be prepared to explain

whether the information will be sold to third parties or stored and reused in the future.

The investigator also should be prepared to explain any measures undertaken to protect data security. The majority of unauthorized disclosures of identifiable health information by investigators occur due to inadequate data security.¹⁷ Even though it is not within the purview of the IRB to enforce the electronic data security standards of the *Code of Federal Regulations* in 21 CFR Part 11 or the HIPAA Security Rule, the investigator should provide information about efforts to comply with these requirements.

Waiver of the HIPAA Privacy Rule

The use of interactive social media to collect information during study recruitment raises additional issues under the HIPAA Privacy Rule. The Privacy Rule prohibits the collection of an individual's personal health information (or PHI) by a covered entity without prior written authorization from that individual.¹⁸ As PHI includes an individual's contact information, including name, age, e-mail address, and mailing address, the Privacy Rule prohibits the collection of contact information via a website without prior authorization.

Some sponsors are looking into the use of social media for the dissemination of post-study results.

This rule creates a conundrum when using social media, as it may be impractical to obtain a written authorization prior to collecting contact information during the recruitment process. To get around this restriction, a researcher generally must obtain a partial waiver of the HIPAA authorization require-

ment.¹⁹ (A waiver in this situation is considered "partial" because it is needed only for the recruitment phase of the clinical study.) A researcher can apply to either an IRB or a privacy board for such a waiver; the researcher will be asked to explain why it is impractical to obtain written authorizations, the plan for collecting information, and the planned safeguards for the data.²⁰

If the researcher plans to keep the data for use in recruiting for future studies, the researcher should apply for a full waiver of authorization for development of the recruitment database. As with the partial waiver, to obtain a full waiver, the researcher will have to explain why it is impractical to obtain written authorizations to store PHI in the database, the plan for collecting information, and the planned safeguards for the data.

Conclusion

Current regulations and guidance set forth enduring principles regarding the protection of human research participants, such as the protection of individuals from coercive, inaccurate, or misleading communications and the protection of individuals' confidential health information. For as long as researchers hold these principles to be valuable, the IRBs will have a role in conducting prospective review of proposed research activities. Emerging technologies in social media provide powerful new tools for researchers, and researchers should be able to take advantage of these tools by working closely with their IRBs to develop appropriate social media communication plans.

Acknowledgments

The author acknowledges Quorum Review Regulatory Attorneys Claire Carbary, Mitchell Parrish, and Deborah Holland for their invaluable assistance in preparing this article.

References

1. Mayo Clinic sees potential of social media in patient recruitment. *CenterWatch News Online* September 1, 2011; available at www.centerwatch.com/news-online/article/2158/mayo-clinic-sees-potential-of-social-media-inpatient-recruitment.
2. Marcus AD. April 25, 2011. ALS study shows social media's value as research tool. *Wall Street Journal*.
3. Dooren JC. June 7, 2011. A clinical drug trial via phone, computer. *Wall Street Journal*.
4. See 45 CFR Part 46, Subpart A.
5. See 21 CFR Parts 50, 56, 312, and 812.
6. U.S. Department of Health and Human Services, Office for Human Research Protections. September 20, 2005. Guidance on Institutional Review Board Review of Clinical Trial Websites. Available at www.hhs.gov/ohrp/policy/clinicaltrials.html.
7. Advance Notice of Proposed Rulemaking. July 26, 2011. 76 *Federal Register*. 44512, 44513.
8. Chretien KC, Azar J, Kind T. 2011. Physicians on Twitter *Journal of the American Medical Association* 305: 566-8.
9. U.S. Department of Health and Human Services. December 2011. Draft Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, p.10.
10. First FDA Draft Guidance on social media leaves clinical trials industry waiting for more. January 9, 2012. *CW Weekly*.
11. U.S. Food and Drug Administration. 2010. Recruiting Study Subjects - Information Sheet. Available at www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.
12. Australian Competition and Consumer Commission vs. Allergy Pathway Pty Ltd and Anor (No.2) FCA 74 (2011).
13. 21 CFR 56.109 (a); 45 CFR 46.109(a); 21 CFR 56.107(a); 45 CFR 46.107(a).
14. 45 CFR Part 164.
15. 21 CFR 56.111(a)(7); 45 CFR 46.111(a)(7).
16. 76 *Federal Register* at 44516.
17. Nass SJ, Levit LA, Gostin LO, eds. 2009. *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. Washington, D.C.: National Academies Press.
18. 45 CFR Sec. 164.508.
19. 45 CFR Sec. 164.512(i)(a)(i).
20. 45 CFR Sec. 164.512(i)(a)(i). **ACRP**

Cami Gearhart, JD, is the CEO of Quorum Review, an independent, accredited IRB in Seattle, Wash. Prior to joining Quorum, she specialized in healthcare regulatory law. She serves on the Board of Directors of the Consortium of Independent Review Boards (CIRB) and the Northwest Association for Biomedical Research (NWABR), and is a graduate of the University of Washington, where she earned a BS in biology and a law degree. She can be reached at cgearhart@quorumreview.com.